REQUEST FOR PROFESSIONAL SERVICES

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SUGGESTED CONTRACTOR:
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SFSU's DUNS #: 942514985

PERIOD OF PERFORMANCE: 30 months from date of issuance, a suggested period of April 15, 2011 - 0ctober 14, 2013. Interim payments are allowed….

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SOLE SOURCE JUSTIFICATION:

The procurement of the services specified in the attached Request for Professional Services is recommended to be processed without full and open competition. The project "An Epidemiologic Health Study of Manganese Exposure in East Liverpool Ohio" was selected by Region 5 to be funded under the Regional Applied Research Effort sponsored by the Office of Science Policy. The proposed contractor, Rosemarie Bowler of San Francisco State University, conducted an air Mn exposure and health outcome study in Marietta, OH and used Mt. Vernon, OH as a control town through U.S. EPA grant number 83416001.The purpose of the current study is to expand the work that was conducted in Marietta and Mt. Vernon to East Liverpool, OH, where air Mn levels are much higher than seen in Marietta. One of the major objectives of this study is to compare results from East Liverpool, OH with the results that were previously collected from Marietta and Mt. Vernon, OH. The proposed contractor collected, analyzed and holds that data from Marietta and Mt. Vernon, OH. The proposed contractor has the capacity of conducting the same protocol as was conducted in the previous two towns (e.g., recruitment,

clinical assessments, biomarker collection). Due to proposed contractor's unique capabilities, it is recommended that this professional services contract be granted without competition.

AUTHORITY AND FAR REFERENCE

The basis for this recommendation is 41 U.S.C. 253(c)(1); FAR 6.302-1; only one responsible source.

STATEMENT OF WORK

A. Background Information

Potential neurotoxicity from airborne Mn exposure has been a community and risk assessment concern for more than a decade in Region 5 (e.g. OH, MI). The RARE program funded a 2009-2010 Mn health study in Marietta OH near a large industrial emitter of airborne Mn, led by Rosemarie Bowler of San Francisco State University. Mt. Vernon OH, demographically similar to Marietta but without large industrial Mn emission sources, was used as the comparison community for Marietta. Initial Marietta-Mt. Vernon comparisons generally indicate a lack of major health effect differences between the two towns. Whether this extends to East Liverpool OH, an area of much higher (up to 50-fold) outdoor air Mn concentrations is the present research question of interest, and a central reason for extending the Marietta-Mt. Vernon study.

Some of the highest chronic US residential Mn inhalation exposure is likely to have occurred in East Liverpool. The proposed work is important in that either positive results (differences between East Liverpool and comparison communities) or negative results (little or no differences among communities) inform the issue of potential health effects of residential airborne Mn exposure, a recognized gap in Mn health effects literature. Both outcomes can also help inform the need for greater airborne Mn control. In addition, the present proposal addresses the USEPA Administrator's environmental justice priority: the poverty rate is higher in East Liverpool (25.2%) than in Marietta (16.9%), Mt. Vernon (15.6%), Ohio (7.8%) or the U.S. (9.2%).

B. Purpose and Objectives

To evaluate whether long term (minimum 10 years) residential airborne Mn exposure can affect human health, this study will compare already-available Marietta and Mt. Vernon adult resident results with those of East Liverpool for biomarkers (blood metals, toenails, hair), medical tests (symptoms; illnesses; Unified Parkinson's Disease Rating Scale evaluation), functional tests (mood; neuropsychological tests [e.g. working memory and attention, verbal skills, motor dexterity/strength, visual tracking speed]) and questionnaires (life style habits; work; dietary Mn). Key research questions include:

- Are blood and plasma Mn (controlled for Cd, Hg, and Pb exposure by measuring these metals in whole blood; controlled for Fe status and liver function by measuring plasma ferritin and the hepatic enzymes ALT and GGT, respectively) significantly elevated in East Liverpool adult residents vs. those in Marietta and Mt. Vernon? An additional novel diagnostic biomarker using toenails and hair shall be used to assess longer term Mn exposure (7-10 months).
- What differences in environmental and lifestyle factors may contribute to blood, hair, and toenail Mn levels in East Liverpool residents?
- Is Mn body burden associated with altered neurological and neuropsychological function, or medical symptoms and illnesses?
- Do health outcomes (e.g. neuropsychological test results) differ among the three towns?
- Can Mn exposure-effect relationships with health and illness be shown through use of a

cumulative exposure index?

C. Specific Objectives/Milestones to be Performed by the Contractor

The contractor will plan, recruit, conduct, analyze the data, and produce reports and manuscripts for this study.

Plan: The contractor shall develop a Quality Assurance Project Plan for the overall study. EPA will provide a template. The contractor shall develop an overall study plan that will include recruitment, data collection, and data analyses. As part of this plan, the contractor shall also provide materials for Institutional Review Board applications. EPA will provide the template. The contractor shall identify an appropriate location to conduct the field study in East Liverpool, OH. The contractor shall provide a plan for estimating air Mn levels in East Liverpool, OH for the study time period. The contractor shall develop a data analyses plan that will include air Mn estimation (either monitor, emissions or modeled) for East Liverpool, OH, assessment of the relationship between Mn exposure and neurologic health outcomes and other health or symptom outcomes, and a comparison of these neurologic health/other health outcomes with the three OH towns (East Liverpool, Marietta, and Mt. Vernon, OH).

Recruit: The contractor shall recruit 100 participants from East Liverpool, OH, between the ages of 30-75 years using the same type of sampling strategy that was used in Marietta, OH and shall have it approved by EPA. Exclusion criteria shall be identical to the Marietta study which include: having had other chemical exposures, less than ten years of residence, working at SH Bell Company (source of Mn emissions) or any industrial company that produces Mn emissions, having had any major illnesses that would affect neurological and/or neuropsychological function, and women pregnant or breastfeeding. To avoid possible groundwater contamination only those residents on municipal water supply shall be eligible to participate. The contractor shall not recruit or go into the field prior to receiving EPA Human Subjects Research Approval, including Institutional Review Board Approval. EPA will obtain this approval.

Conduct: The contractor shall conduct the study based upon an EPA approved study plan. The contractor shall provide a $50 gift card from a local store as an incentive to each participant who completes the study.

The contractor shall have the following stations and personnel able to conduct the activity at each the stations: 1.) welcome area where the consent process and health questionnaire completion can occur; 2.) laboratory area with the following capabilities – a phlebotomist that will collect blood samples both whole blood and serum, centrifuge for processing blood samples, place to store blood samples both refrigerated and frozen, equipment that follows all universal precautions, an area where toenails and hair samples can be collected if not brought in from home from the participant, a person qualified to process all samples and prepare them to be shipped to appropriate laboratories; 3.) multiple neurological testing areas with trained and qualified practitioners in administering the tests that shall be consistent with what was done in Marietta, OH and identified by the contractor and will be approved by EPA (e.g., UPDRS, CATSYS, Cognitive, Motor and Tremor, Mood).

The contractor shall test the following biomarkers in the human samples collected: whole blood: metals panel including Mn, toenail Mn levels, hair Mn levels. EPA will test serum Ferritin and liver enzymes.

Analyses/Reports/Manuscripts: Once the data analyses plan is approved by EPA, the contractor shall analyze the data, write up reports based on the data and write manuscripts based on the data analyses for appropriate peer reviewed journals.

D. Government Responsibilities

The government researchers will be responsible for obtaining EPA Human Subjects Approval, for providing templates for QAPP and IRB.